Karen A. Confoy, Esq.
Erica S. Helms, Esq.
STERNS & WEINROTH, P.C.
50 West State Street, Suite 1400
Trenton, NJ 08607-1298
Tel. (609) 989-5012
Facsimile (609) 392-7956
Attorneys for Defendants and Counter-Plaintiffs
Lupin Ltd. and Lupin Pharmaceuticals, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA WOMEN'S HEALTH, INC., Plaintiff and Counter-Defendant, v. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC. Defendants and Counter-Plaintiffs.	**DOCUMENT FILED ELECTRONICALLY** Civil Action No. 2:10-cv-00603 (PGS) (ES)

ANSWER AND COUNTERCLAIMS OF
LUPIN PHARMACEUTICALS, INC. AND LUPIN, LTD.

Defendants and Counter-Plaintiffs Lupin Pharmaceuticals, Inc., ("LPI") having its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202, and Lupin Limited ("Lupin Ltd."), having its principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India (collectively, "Lupin"), by and through their attorneys, respond to each of the numbered paragraphs to the Complaint filed against it by Plaintiff and Counter-Defendant Teva Women's Health, Inc. ("Teva") as follows:

NATURE OF THE ACTION

1. Lupin admits that this action for alleged infringement of U.S. Patent No. 7,320,969 ("the '969 patent") purports to arise under the patent laws of the United States.

THE PARTIES

2. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint, and therefore denies them.

3. Lupin admits the allegations in paragraph 3 of the Complaint.

4. Lupin admits that LPI is a corporation organized under the laws of the Commonwealth of Virginia, with a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin admits that LPI is a wholly owned subsidiary of Lupin Ltd. To the extent that there are any remaining allegations in paragraph 4 of the Complaint, Lupin denies them.

5. Lupin admits that Lupin Ltd. develops and manufactures pharmaceutical products for sale in the United States. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin Ltd. and LPI, but denies the remaining allegations in paragraph 5 of the Complaint.

JURISDICTION AND VENUE

6. Lupin admits that subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) is proper for the claims directed against Lupin Ltd. only. Lupin denies that subject matter jurisdiction exists over the claim of infringement based on 35

U.S.C. § 271(e) insofar as it is directed to LPI. To the extent there are any remaining allegations in paragraph 6 of the Complaint, Lupin denies them.

7. LPI admits that it engages in the sale of pharmaceutical products within the United States and New Jersey and, for the purposes of this action only, does not contest that this Court has personal jurisdiction over it. Lupin Ltd. denies that it engages in the sale of pharmaceutical products within the United States generally and the State of New Jersey specifically, and otherwise is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 7 of the Complaint, and therefore denies them.

8. Lupin does not contest that venue is proper as to it in this Court. To the extent there are any remaining allegations in paragraph 8 of the Complaint, Lupin denies them.

BACKGROUND

9. On information and belief, Lupin admits that on January 22, 2008 the United States Patent and Trademark Office ("PTO") issued the '969 patent, entitled "Oral Contraceptives To Prevent Pregnancy and Diminish Premenstrual Symptomatology," to Duramed Pharmaceuticals, Inc. ("Duramed"), now known as Teva Women's Health, Inc. Lupin admits that the '969 patent lists Robert G. Bell, Carole Ben-Maimon, and Beata Iskold as the inventors and that a copy of the '969 patent is attached to the Complaint as Exhibit A. Lupin denies that the '969 patent was "duly and legally" issued by the PTO or that the '969 patent is valid and enforceable.

Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 9 of the Complaint, and therefore denies them.

10. Lupin admits that the '969 patent is directed to a method of female contraception which comprises administering to the female a dosage comprising a combination of estrogen and progestin for a period of 81 to 89 consecutive days, followed by administration of a dosage consisting essentially of estrogen for a period of 2 to 8 consecutive days, wherein the estrogen that is administered in combination with progestin for the period of 81 to 89 consecutive days is administered in a daily amount equivalent to about 10 μg to about 50 μg of ethinyl estradiol, the estrogen that is administered for a period of 2 to 8 consecutive days is administered in a daily amount equivalent to about 5 μg to about 10 μg of ethinyl estradiol, and the progestin that is administered for the period of 81 to 89 consecutive days is administered in a daily amount of about 150 μg of levonorgestrel. To the extent there are any remaining allegations in paragraph 10 of the Complaint, Lupin denies them.

11. On information and belief, Lupin admits that the United States Food and Drug Administration ("FDA") approved New Drug Application No. 21-840 allowing Duramed to sell an oral contraceptive product in the United States under the trade name Seasonique®. On information and belief, Lupin admits that Seasonique® includes 84 combination tablets containing 30 μg of ethinyl estradiol and 150 μg of levonorgestrel as the active ingredients and 7 tablets containing 10 μg of ethinyl estradiol as the active ingredient. To the extent there are any remaining allegations in paragraph 11 of the Complaint, Lupin denies them.

12. Lupin admits the allegations in paragraph 12 of the Complaint.

LUPIN'S ACTS GIVING RISE TO THIS ACTION

13. Lupin admits that Lupin Ltd. notified Duramed Pharmaceuticals, Inc., Barr Laboratories, Inc., Teva Pharmaceuticals, USA, Teva Women's Health, Inc. and Teva Corporate Headquarters by letter dated December 22, 2009 that Lupin Ltd. had submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 91-467 seeking approval to manufacture, sell and distribute a product comprising 84 tablets containing 30 µg ethinyl estradiol and 150 µg levonorgestrel and 7 tablets containing 10 µg ethinyl estradiol ("the Lupin Product"). To the extent there are any remaining allegations in paragraph 13 of the Complaint, Lupin denies them.

14. Lupin admits that the purpose of Lupin Ltd.'s filing of ANDA No. 91-467 is to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use and sale of the Lupin Product prior to the expiration of the '969 patent. To the extent there are any remaining allegations in paragraph 14 of the Complaint, Lupin denies them.

15. Lupin admits that Lupin Ltd. submitted its ANDA No. 91-467 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that the claims of the '969 patent are invalid and/or will not be infringed by the manufacture, use or sale of the Lupin Product. To the extent that there are any remaining allegations in paragraph 15 of the Complaint, Lupin denies them.

16. Lupin denies the allegations in paragraph 16 of the Complaint.

17. Lupin admits that in Lupin Ltd.'s notice letter, Lupin Ltd. indicated that it filed ANDA No. 91-467 seeking FDA approval to commercially sell and market the Lupin Product within the United States (including the State of New Jersey) prior to the expiration of the '969 patent. To the extent that there are any remaining allegations in paragraph 17 of the Complaint, Lupin denies them.

18. Lupin admits that Lupin Ltd.'s notice letter provided a statement of the legal and factual basis for its belief that the '969 patent is invalid or that the claims of the '969 patent will not be infringed by the manufacture, use or sale of the Lupin Product. Lupin denies the remaining allegations of paragraph 18 of the Complaint.

19. Lupin admits the allegations in paragraph 19 of the Complaint.

20. Lupin admits the allegations in paragraph 20 of the Complaint.

21. Lupin admits that Teva filed the Complaint within 45 days of the date it received Lupin's notice letter dated December 22, 2009. To the extent there are any remaining allegations in paragraph 21 of the Complaint, Lupin denies them.

COUNT I: PATENT INFRINGEMENT OF U.S. PATENT NO. 7,320,969

22. Lupin incorporates by reference its answers to paragraphs 1 to 21 of the Complaint as if restated fully herein.

23. Lupin denies the allegations in paragraph 23 of the Complaint.

24. Lupin denies the allegations in paragraph 24 of the Complaint.

25. Lupin denies the allegations in paragraph 25 of the Complaint.

26. Lupin denies the allegations in paragraph 26 of the Complaint.

27. Lupin denies the allegations in paragraph 27 of the Complaint.

28. Lupin denies the allegations in paragraph 28 of the Complaint.

29. Lupin denies the allegations in paragraph 29 of the Complaint.

DEFENSES

Further responding to the Complaint, and as additional defenses thereto, Lupin asserts the following defenses, without admitting any allegations of the Complaint not otherwise admitted and without assuming any burden when such burden would otherwise be on Teva.

FIRST DEFENSE
(Invalidity of the '969 Patent)

30. One or more claims of the '969 patent are invalid for failing to meet a condition for patentability set forth in 35 U.S.C. § 101 *et seq.* By way of example and not of limitation, claims 1-9, 15, and 17-19 of the '969 patent are invalid under 35 U.S.C. § 103 over United States Patent Number 5,898,032 in view of United States Patent Number 6,027,749.

SECOND DEFENSE
(Noninfringement of the '969 Patent)

31. No valid claim of the '969 patent is infringed by the Lupin Product.

THIRD DEFENSE
(Failure to State a Claim)

32. To the extent that Teva alleges that submission of ANDA No. 91-467 makes this case exceptional under 35 U.S.C. § 285, the Complaint fails to state a claim upon which relief can be granted and must be dismissed.

FOURTH DEFENSE
(Improper Party)

33. LPI is not a proper party to this action.

COUNTERCLAIMS

Further responding to the Complaint, Lupin alleges the following counterclaims, without admitting any allegations of the Complaint not otherwise admitted and without assuming the burden when such burden would otherwise be on Teva.

THE PARTIES

1. Lupin Limited ("Lupin Ltd.") is an Indian corporation having a place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

2. Lupin Pharmaceuticals, Inc. ("LPI") is a Virginia corporation having a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

3. Upon information and belief, Teva Women's Health, Inc. ("Teva") is a corporation organized and existing under the laws of the State of Delaware, having an established place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and pursuant to 35 U.S.C. § 271(e)(5), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et seq.*

5. This Court has personal jurisdiction over Teva by virtue of the fact that Teva conducts business in the State of New Jersey, has availed itself of the rights and benefits of New Jersey law, and has engaged in substantial and continuing contacts with New Jersey.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

THE CONTROVERSY

7. Lupin Ltd. holds Abbreviated New Drug Application ("ANDA") No. 91-467 for a product comprising 84 tablets containing 30 µg ethinyl estradiol and 150 µg levonorgestrel and 7 tablets containing 10 µg ethinyl estradiol ("the Lupin Product").

8. On or about February 3, 2010, Teva filed the present action against Lupin alleging infringement of U.S. Patent No. 7,320,969 ("the '969 patent") arising from Lupin Ltd.'s submission of ANDA No. 91-467. There is a substantial controversy between the parties by reason of the commencement by Teva of this action and the filing by Lupin Ltd. of ANDA 91-467 with a certification that the '969 patent is invalid and/or will not be infringed by the manufacture, sale and use of the Lupin Product. Lupin and Teva have adverse legal interests with respect to the '969 patent of sufficient immediacy

and reality to warrant the issuance of a declaratory judgment. The '969 patent effectively prevents approval of Lupin Ltd.'s ANDA product by the United States Food and Drug Administration.

COUNT I

(Declaratory Judgment of Invalidity of the '969 Patent)

9. Lupin repeats and incorporates by reference paragraphs 1 to 8 of its Counterclaims.

10. One or more claims of the '969 patent are invalid for failing to meet a condition for patentability set forth in 35 U.S.C. § 101 *et seq*. By way of example and not of limitation, claims 1-9, 15, and 17-19 of the '969 patent are invalid under 35 U.S.C. § 103 over United States Patent Number 5,898,032 in view of United States Patent Number 6,027,749.

COUNT II

(Declaratory Judgment of Non-Infringement of the '969 Patent)

11. Lupin repeats and incorporates by reference paragraphs 1 to 10 of its Counterclaims.

12. No valid claim of the '969 patent is infringed by the Lupin Product.

PRAYER FOR RELIEF

WHEREFORE, Lupin respectfully requests the Court enter judgment against Plaintiff and Counter-Defendant Teva to include:

(a) a declaration that Lupin's commercial manufacture, use, offer for sale, sale, or importation of its ANDA product will not infringe any valid claim of the '969 patent;

(b) a declaration that one or more claims of the '969 patent are invalid;

(c) a declaration that Teva is entitled to no damages, interest, costs, or other relief from or against Lupin for infringement of the '969 patent pursuant to 35 U.S.C. § 271 (e)(4), 35 U.S.C. § 285, or any other provision of law;

(d) such other and further relief as the Court may deem just and proper.

STERNS & WEINROTH, P.C.
Attorneys for Defendants and Counter-Plaintiffs LUPIN PHARMACEUTICALS, INC. and LUPIN, LTD.

By: /s/ Karen A. Confoy
Karen A. Confoy
kconfoy@sternslaw.com

Dated: March 19, 2010

OF COUNSEL:

Douglass C. Hochstetler
Sailesh K. Patel
Jessica K. Fender
SCHIFF HARDIN LLP
233 S. Wacker Drive, Suite 6600
Chicago, IL 60606
(312) 258-5500
Attorneys for Defendants and Counter-Plaintiffs LUPIN PHARMACEUTICALS, INC. and LUPIN, LTD.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2 AND 40.1 OF LUPIN PHARMACEUTICALS, INC. AND LUPIN, LTD.

Pursuant to Local Civil Rule 11.2 and 40.1, Defendants and Counter-Plaintiffs Lupin Pharmaceuticals, Inc. and Lupin Limited, by their attorneys, hereby certify to the best of their knowledge and belief that the matter in controversy, particularly the patent-in-suit (U.S. Patent No. 7,320,969) in the above-captioned matter, is the subject of the following action:

TEVA WOMEN'S HEALTH, INC. v. MYLAN PHARMACEUTICALS, INC., MYLAN INC., & FAMY CARE LTD., 2:10-cv-01235-PGS-ES (District of New Jersey)

DURAMED PHARMACEUTICALS, INC. v. WATSON LABORATORIES, INC. & WATSON PHARMACEUTICALS, INC., 3:08-cv-00116-LRH-RAM (District of Nevada)

I certify that the foregoing statements are within my personal knowledge pursuant to Local Civil Rule 7.2.

/s/ Karen A. Confoy
Karen A. Confoy
kconfoy@sternslaw.com

Dated: March 19, 2010

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing ANSWER AND COUNTERCLAIMS OF LUPIN PHARMACEUTICALS, INC. AND LUPIN, LTD. was electronically filed with the Clerk of Court using CM/ECF on March 19, 2010 which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

The undersigned further certifies that on March 19, 2010 the attached document was served to the following persons by email addressed as follows:

Robert G. Krupka, P.C.
Alexander F. MacKinnon
333 South Hope Street, 29th Floor
Los Angeles, California 90071
bob.krupka@kirkland.com
alexander.mackinnon@kirkland.com

Charanjit Brahma
Corey Manley
655 Fifteenth Street, N.W.
Washington, DC 20005
charanjit.brahma@kirkland.com
corey.manley@kirkland.com

Allyn Z. Lite
Michael E. Patunas
Mayra V. Tarantino
LITE DEPALMA GREENBERG LLC
Two Gateway Center, 12th Floor
Newark, NJ 07102-5003
alite@ldgrlaw.com
mpatunas@ldgrlaw.com
mtarantino@ldgrlaw.com

/s/ Karen A. Confoy
Karen A. Confoy
kconfoy@sternslaw.com